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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/031,913	05/21/2002	Jose Castillo Deniega	IFLOW.063NP	2831

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EXAMINER

MACNEILL, ELIZABETH

ART UNIT	PAPER NUMBER
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3767

NOTIFICATION DATE	DELIVERY MODE
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12/04/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No. 10/031,913	Applicant(s) DENIEGA ET AL.	
	Examiner ELIZABETH R. MACNEILL	Art Unit 3767	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 October 2008.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 18,20,21,23-28,73 and 76-85 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 18,20,21,23-28,73 and 76-85 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>10/14/08</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 14 October 2008 has been entered.

2. All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

1. Claims 18, 20, 21, 23-28, 73 and 76-85 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ekholmer (US 4,717,379).

Ekholmer teaches a catheter comprising an elongated support (5) constructed from a first material; and a porous membrane (distal portion of the catheter, see that pores 4 do not appear at the proximal end of the catheter in Fig 1 and Fig 4) constructed from a second material that is wrapped around an entire circumference of the support (Fig 2), said support having a lumen between the porous membrane and the support (3), where fluid enters the proximal end of the lumen and exits through the pores (4, Fig 1). The catheter further includes a tubular, non-porous membrane (proximal end of 1, which does not have pores 4, Fig 1 and Fig 4) which is wrapped around the support. As to the uniform flow from the entire infusion section, see Fig 1 showing a uniform flow (arrows leaving pores 4).

Ekholmer does not expressly disclose (1) that the first and second membranes are made of a different material or (2) that the porous and non-porous sections of catheter 1 are "separate."

(1) The cross-hatchings in the figures indicate that they are different materials, as well as the description (Col 2 lines 20-40) of making the catheter. Additionally, a porous membrane is generally flexible and may be difficult to position in the body without extra support, so it would be beneficial to provide a more rigid support. It would have been obvious to one of ordinary skill in the art at the time the invention was made to use two different materials for the support and porous membrane as this is suggested by the drawings and description and would provide the additional benefit of having a more rigid inner catheter.

(2) Furthermore, it would have been obvious to one of ordinary skill in the art at the time the invention was made make the porous and non-porous section separate since it has been held that constructing a formerly integral structure in various elements involves only routine skill in the art. An added benefit of making the porous and nonporous membranes separate would be that the medical personnel could customize the length of each piece (and therefore the infusion area) based on the patient's anatomy and desired treatment. For example, a small child might need to shorter catheter and a shorter infusion section than a full grown man. Without separate sections, the physician would only be able to shorten the overall length of the catheter, not both the infusion

section and overall length. See MPEP 2144.04 (V) (C), *In re Dulberg*, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is “press fitted” and therefore not manually removable. The court held that “**if it were considered desirable for any reason** to obtain access to the end of [the prior art’s] holder to which the cap is applied, **it would be obvious to make the cap removable** for that purpose.”). Emphasis added.

As to claim 20, 21, 27, 73, 80, 82, 83 see “Of course it would be possible to instead provide the inner tube 3 with longitudinal partitions 7 on the outside, at which the outer tube 6 can be plane” and Fig 2, which shows ribs (7) that porous membrane (1) is wrapped around. See also Fig 3 for “dome-shaped end portion.”

As to claim 85, see Fig 4, non-porous membrane (8).

As to claim 23, 24, 76, 77 see Fig 2 and paragraph spanning Col 1-2, which suggests all the passages are separate.

As to claim 25, 78, 84 the device must be somewhat flexible in order to be guided into the body for a long insertion time and without irritation (Summary of the Invention)

As to claim 26, 79 guidewire lumen (2)

As to claim 28, 81 Ekholmer does not disclose the dimension of the pores. Instead, they are described as “very small capillary holes.” It would have been obvious to one of ordinary skill in the art at the time the invention was made to use pores of less than

.023 microns since it has been held that selecting an optimum dimension involves only routine skill in the art. *In re Boesch*, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

Response to Arguments

Applicant's arguments with respect to claims 18, 20, 21, 23-28, 73 and 76-85 have been considered but are not persuasive. Applicant argues that Ekholmer does not teach a uniform flow through porous membrane. This is illustrated in Fig 1 with arrows showing flow out of every pore 4 of the porous membrane. See also "The capillaries 4 are by capillary action filled with more agent as long as a sufficient amount of agent is present in the axial passages 3" which indicates that the pores are saturated along the entire length of the porous infusion section. The rejection is maintained.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to ELIZABETH R. MACNEILL whose telephone number is (571)272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Simons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Elizabeth R MacNeill/
Examiner, Art Unit 3767
/Kevin C. Sirmons/
Supervisory Patent Examiner, Art Unit 3767